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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/082,706	02/25/2002	Theodore H. Superak	N1305-025	5310

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EXAMINER

KUBELIK, ANNE R

ART UNIT PAPER NUMBER

1638

DATE MAILED: 11/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<p align="center"><b>Office Action Summary</b></p>	<b>Application No.</b> 10/082,706	<b>Applicant(s)</b> SUPERAK ET AL.	
	<b>Examiner</b> Anne R. Kubelik	<b>Art Unit</b> 1638	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 August 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5, 7-10 and 34-46 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 1-5, 7-10 and 34-42 is/are allowed.
- 6) ☒ Claim(s) 43-46 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
       Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
       If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
       a) ☐ All    b) ☐ Some \*    c) ☐ None of:  
           1. ☐ Certified copies of the priority documents have been received.  
           2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
           3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
       \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
       a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

1. Claims 1-5, 7-10 and 34-46 are pending.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Withdrawn Objections and Rejections***

3. The objection to claims 1, 7, 9 and 18 for the inclusion of a blank line where the ATCC Accession number should be is withdrawn in light of Applicant's assertion that a deposit to the ATCC will be made upon allowance.
4. The objection to claim 8 because of the informalities is withdrawn in light of amendment to the claim.
5. The rejection of claims 1-33 under 35 USC 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is withdrawn in light of applicant's statement that
  - (a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;
  - (b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
  - (c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the enforceable life of the patent, whichever is longer;
  - (d) the viability of the biological material at the time of deposit will be tested (see 37 CFR 1.807); and
  - (e) the deposit will be replaced if it should ever become inviable.
6. The rejection of claims 1-33 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention is withdrawn in light of amendment to the claims.

***Claim Objections***

7. Claim 43 is objected to because it recites “a characteristics” in line 3; either “a” should be deleted, or “characteristics” should be singular.

***Claim Rejections - 35 USC § 112***

8. Claims 43-46 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is repeated for the reasons of record as set forth in the Office action mailed 3 April 2003, as applied to claims 6, 11-13, 15-17 and 19-33. Applicant's arguments filed 4 August 2003 have been fully considered but they are not persuasive.

The claims are drawn to hybrid and gene-converted squash plants, wherein it remains unclear what the identity of the plants in each of the steps would be, much less what the resultant product plant would be. Neither the plants required by each of the steps, nor the plants that are produced by the process are defined by genomic structure or by all their phenotypic characteristics, and therefore, the claimed invention lacks an adequate written description.

Applicant urges that as long as a line is self-pollinated, the genotype and phenotype is stable (response pg 6). This is not found persuasive because Applicant is arguing a limitation (self-pollination) not in the claims.

Applicant urges that because an inbred has a homozygous genome, all gametes will be identical and carry a copy of each parental chromosome. Applicant urges that thus the genome of the inbred is present in the hybrid. Applicant urges that as long as the homozygosity of the

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parental lines is maintained, the resulting hybrid cross will be genetically and phenotypically stable (response pg 6-7).

This is not found persuasive because crossing the inbred with plant of another genotype means the resulting hybrid has a genotype and phenotype that is different from that of its parents.

Applicant urges that the F1 hybrid is a combination of the phenotypic characteristics from the two arrangements and organizations of the genes. Applicant also urges that the creation of the F1 is thus highly predictable; dominant alleles present and expressed in the inbred will be expressed by the F1 hybrid (response pg 7). This is not found persuasive because those dominant alleles have not been described. What is the phenotype of the claimed hybrid? What are their genotypes?

Applicant urges that new claims 45 and 46 have 50% of their genetic material from the gametes of the inbred line and thus satisfy the provision of 35 USC 112, 1<sup>st</sup> paragraph (response pg 7). This is not found persuasive because the entire genotype and phenotype of the claimed hybrids have not been described.

Applicant urges that when the F1 itself produced gametes, the genetic arrangement is not predictable due to meiotic recombination and to homologous recombination (response pg 7-9). This is agreed.

9. Claims 43-44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claim is broadly drawn to plants having all of the physiological and morphological characteristics of the plant of claim 2 but further comprising one or more single gene transferred traits, seeds from the plant and soybean breeding methods using it.

The instant specification, however, only provides general guidance for backcrossing (pg 9). The instant specification fails to provide guidance for transferring only a single gene by crossing from one plant to another, especially via a single backcross.

Kraft et al (2000, Theor. Appl. Genet. 101:323-326) teach that linkage disequilibrium effects and linkage drag prevent the making of plants comprising a single gene conversion, and that such effects are unpredictably genotype specific and loci-dependent in nature (pg 323, column 2, line 7 to line 15). Kraft et al teach that linkage disequilibrium is created in breeding materials when several lines become fixed for a given set of alleles at a number of different loci, and that very little is typically known about the plant breeding materials, and therefore it is an unpredictable effect in plant breeding (pg 323, column 2, line 7 to line 15).

The instant specification does not teach how to overcome these problems.

Given the claim breadth, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to develop and evaluate plants comprising a single gene transferred trait.

***Claim Rejections - 35 USC § 102 - 35 USC § 103***

10. Claims 44-46 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103 as obvious over Miller et al (US Patent 6,031,158). The rejection is repeated for the reasons of record as set forth in the Office action mailed 3 April 2003, as applied to

claims 6, 11-13, 15-17 and 19-33. Applicant's arguments filed 4 August 2003 have been fully considered but they are not persuasive.

Applicant urges that claims 6, 11-13, 15-17 and 19-33 have been cancelled.

Additionally, Applicant urges that the squash of Miller et al is susceptible to powdery mildew while the instant squash is resistant (response pg 11). This is not found persuasive because the hybrid and gene converted plants are not limited to plants that are resistant to powdery mildew.

11. Claims 44-46 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103 as obvious over Superak (US Patent 5,959,184). The rejection is repeated for the reasons of record as set forth in the Office action mailed 3 April 2003, as applied to claims 6, 11-13, 15-17 and 19-33. Applicant's arguments filed 4 August 2003 have been fully considered but they are not persuasive.

Applicant urges that claims 6, 11-13, 15-17 and 19-33 have been cancelled (response pg 11). This is not found persuasive because the hybrid and gene converted plants have not been described, as discussed above.

### ***Double Patenting***

12. Claims 44-46 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 6, 11-13, 15-17 and 19-33 of copending Application No. 10/082,707. Although the conflicting claims are not identical, they are not patentably distinct from each other. The rejection is repeated for the reasons of record as set forth in the Office action mailed 3 April 2003, as applied to claims 6, 11-13, 15-17 and 19-33. Applicant's arguments filed 4 August 2003 have been fully considered but they are not persuasive.

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Applicant urges that squash of 835 line and those of 833 line are different and would lead to different hybrids; for example, 835 is a mid-season medium green zucchini, 833 is a mid season gray zucchini (response pg 11-12). This is not found persuasive because the hybrid and gene converted plants have not been described, as discussed above.

13. Claims 1-5,7-10 and 34-42 are allowed.

***Conclusion***

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (703) 308-5059. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service at (703) 308-0198.

Anne R. Kubelik, Ph.D.  
November 12, 2003

